REMARKS

Claims 1, 4, 5 and 8-22 currently appear in this application. The Office Action of June 27, 2008, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicant respectfully requests favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Claim Amendments

The limitations of claim 7 have been incorporated into claim 1.

The phrase "4.0' has been added to claims 1 and 18, based upon the specification at page 15, line 19.

The phrase "0 to 300 mS/m" in claim 4 has been amended to "300 mS/m or less."

Art Rejections

Claims 1, 6 and 17 remain rejected under 35 U.S.C. 102(b) as being anticipated by Faupel et al., US 4,971,670.

This rejection is respectfully traversed. Claim 7 has not been rejected as anticipated by Faupel. The limitations of claim 7 have been incorporated into claims 1 and 17. Claim 6 has been cancelled, so this rejection is now moot with respect to claim 6.

Claims 1, 4 and 5 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Faupel in view of Naveh et al., EP 0 313 343.

This rejection is respectfully traversed. Claims 1, 4 and 5 have been amended to in incorporate the limitations of claim 7, namely, that the impurity removed is DNA contaminants. This is neither disclosed nor suggested in either of Faupel or Naveh, either alone or in combination, as claim 7 has not been rejected by this combination. Accordingly, it is believed that claims 1, 4 and 5 are now allowable.

Claims 1, 9, 10 19 and 20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Faupel in view of Vedantham et al., US Published Application No. 2003/0166869.

This rejection is respectfully traversed. First of all, it is respectfully submitted that it is not appropriate to combine Faupel with Vedantham, because Faupel discloses electrophoresis, which is completely different from the affinity chromatography disclosed in Vedantham. In electrophoresis, components are separated under the influence of an electric current. On the other hand, there is no application of electric current in an affinity chromatography process. That is, the principle of electrophoresis to separate components is completely different from that of affinity chromatography, and there is no reason that one skilled in the art would substitute an affinity chromatography for an electrophoretic separation. Accordingly, it is respectfully submitted that there is no motivation to apply conditions used in an electrophoresis process

of Faupel to an affinity chromatography process as disclosed in Vedantham.

Furthermore, claim 19 is drawn to removing DNA contaminants, which cannot be removed from an antibody-containing sample using affinity chromatography, as particles from the eluate by adjusting the pH of the eluate from 4.0 to equal to or lower than the isoelectric point of the antibody. Claim 19 does indeed use affinity chromatography, but the chromatography is on Protein A or G, not hydoxyapatite. However, as noted above the affinity chromatography is supplemented by lowering the pH to form particles which then precipitate. It is respectfully submitted that the feature of claim 19 for removing DNA contaminants by forming particles thereof can easily be understood from the specification as filed, unparticular from the working examples. This feature is neither disclosed nor suggested in the combination of Faupel and Vedantham.

As recited in claim 19, an antibody-containing sample is subjected to affinity chromatography, which is then eluted with an acidic aqueous solution of low conductivity having a concentration of 100 mM or less, whereby an antibody-containing solution having a concentration of 100 mM or les is prepared. Although some DNA contaminants could be removed in the chromatography process, this affinity chromatography cannot sufficiently remove DNA contaminants and hence the resultant eluate (the antibody-containing solution) contains a certain amount of DNA contaminant. This is shown in, for example, example 2 of the present application. Thus, as a next step, the pH of the eluate is adjusted to from 4.0 to equal to or lower than the isolelectric point of the antibody, whereby DNA contaminants contained in the eluate are precipitated as particles, which particles can be removed by filtration and the like.

Rejections under 35 U.S.C. 112

Claims 1, 4-7, 9, 10 and 17-20 are rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement. The Examiner alleges that the limitation "having a concentration of 100 mM or less" is new matter.

This rejection is respectfully traversed. The specification as filed at page 14, lines 6-8, states that the solution is one of low conductivity, which has a molarity of 0 to 100 mM. This molarity is not simply the concentration of a protein contained in the solution, but relates to the concentration of solute, which directly relates to the conductivity of the solution.

Claims 1, 4-7, 9, 10 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner's position is that the limitation "100 mM or less" includes zero, so that the claims include a protein containing

sample that has a concentration of protein that is less than zero.

This rejection is respectfully traversed. One of the characteristic features of the presently claimed process is to maintain the molarity of the solution at 100 mM or less and to control the pH of the solution from 4.0 to equal to or lower than the isoelectric point of the protein respectively, whereby DNA contaminates can be effectively removed from a sample without the need to use a complicated process. That is, regarding molarity, the upper limit of molarity is critical to the presently claimed process, which is clear to one skilled in the art. Although the wording "100 mM or less" is not present *in n haec verba* in the specification (which, as the Examiner is well aware, is not required), one skilled in the art would clearly understand that a molarity of 0 mM is not proper, and that an appropriate molarity of 100 mM or less (and clearly greater than 0 mM) is applicable to the presently claimed process. For the same reason, the phrase

"300 mS/m or less" also clearly indicates that o mS/m is not operable and therefore is not covered by the present claims.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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